Docket No.: P0741.70006US00

## **AMENDMENTS TO THE CLAIMS**

11

Please replace all prior versions, and listings, of claims in the application with the following list of claims:

- 1-47. (Canceled)
- 48. (Currently Amended) A composition comprising <u>an isolated dimer of PSMA</u> protein in a solution that <u>has a pH in the range of 6 to 7.5</u>, wherein the composition further comprises at least one type of metal ions, and at least one salt, wherein the at least one salt is present at a concentration in the range of 100mM to 300mM, and wherein the sequence of each PSMA protein comprises the sequence set forth as SEQ ID NO: 1, or a portion thereof promotes or preserves multimeric association of PSMA protein.
- 49-50. (Canceled)
- 51. (Currently Amended) The composition of claim <u>48</u>[[50]], wherein the solution-that promotes or preserves dimeric association of PSMA protein has a pH of 7.5that ranges from 5 to 7.
- 52. (Currently Amended) The composition of claim <u>48</u>[[51]], wherein the solution-that promotes or preserves dimeric association of PSMA protein has a pH of 7that ranges from 5.5 to 7.
- 53. (Currently Amended) The composition of claim <u>48</u>[[51]], wherein the solution-that promotes or preserves dimeric association of PSMA protein has a pH of 6.5.
- 54. (Canceled)
- 55. (Currently Amended) The composition of claim <u>48</u>[[54]], wherein <u>onethe cationic</u> component of the salt is sodium, potassium, ammonium, magnesium, calcium, <u>or zinc or a combination thereof</u>,

and wherein another the anionic component of the salt is chloride, sulfate, or acetate or a combination thereof.

- 56. (Original) The composition of claim 55, wherein the salt is sodium chloride, sodium sulfate, sodium acetate or ammonium sulfate.
- 57-58. (Canceled)
- 59. (Currently Amended) The composition of claim <u>48</u>[[58]], wherein the salt is present at a concentration of 150mM.
- 60. (Currently Amended) The composition of claim <u>48</u>[[57]], wherein the composition further comprises at least one[[an]] adjuvant.
- 61. (Currently Amended) The composition of claim <u>48</u>[[57]], wherein the composition is physiologically acceptable.
- 62. (Canceled)
- 63. (Currently Amended) The composition of claim <u>48</u>[[62]], wherein the metal ions are zinc ions, calcium ions, magnesium ions, cobalt ions, <u>or manganese ions or a combination thereof.</u>
- 64. (Currently Amended) The composition of claim <u>48</u>[[63]], wherein the metal ions are zinc ions and calcium ions.
- 65. (Original) The composition of claim 64, wherein the zinc ions and calcium ions are present at a concentration in the range of 0.1mM to 5mM.
- 66. (Original) The composition of claim 64, wherein the zinc ions are present at a concentration that is lower than the concentration of the calcium ions.

- 67. (Original) The composition of claim 66, wherein the zinc ions are present at a concentration of 0.1mM and the calcium ions are present at a concentration of 1mM.
- 68. (Original) The composition of claim 63, wherein the metal ions are magnesium ions.
- 69. (Original) The composition of claim 68, wherein the magnesium ions are present at a concentration in the range of 0.1mM to 5mM.
- 70. (Original) The composition of claim 69, wherein the magnesium ions are present at a concentration of 0.5mM.
- 71. (Currently Amended) The composition of claim 48, wherein the solution that promotes or preserves dimeric association of PSMA protein is free of chelating agents.
- 72. (Previously Presented) The composition of claim 48, wherein the composition further comprises at least one buffer.
- 73. (Currently Amended) The composition of claim 72, wherein the at least one buffer is PBS (phosphate buffered saline), citric acid, sodium citrate, sodium acetate, acetic acid, sodium phosphate, phosphoric acid, sodium ascorbate, tartartic acid, maleic acid, glycine, sodium lactate, lactic acid, ascorbic acid, imidazole, sodium bicarbonate, carbonic acid, sodium succinate, succinic acid, histidine, sodium benzoate, or benzoic acid or a combination thereof.
- 74. (Previously Presented) The composition of claim 48, wherein the composition further comprises a free amino acid, wherein the free amino acid is naturally occurring or non-naturally occurring.
- 75. (Original) The composition of claim 74, wherein the naturally occurring or non-naturally occurring free amino acid is a non-acidic free amino acid.

Confirmation No. 4456

76. (Currently Amended) The composition of claim 75, wherein the non-acidic free amino acid is glycine, proline, isoleucine, leucine, alanine, <u>or arginine or a combination thereof.</u>

- 77. (Previously Presented) The composition of claim 48, wherein the composition further comprises a surfactant.
- 78. (Currently Amended) The composition of claim 77, wherein the surfactant is <u>polysorbate</u> <u>20Tween20</u>, <u>polysorbate 80Tween80</u>, Triton X-100, dodecylmaltoside, cholic acid, <u>or CHAPS-or a combination thereof.</u>
- 79. (Currently Amended) The composition of claim 48, wherein the composition further comprises a cryoprotectant, an antioxidant, or a preservative or a combination thereof.
- 80. (Original) The composition of claim 79, wherein the cryoprotectant is a sugar, a polyol, an amino acid, a polymer, an inorganic salt, an organic salt, trimethylamine N-oxide, sarcosine, betaine, gamma-aminobutyric acid, octapine, alanopine, strombine, dimethylsulfoxide or ethanol.
- 81. (Original) The composition of claim 80, wherein the sugar is sucrose, lactose, glucose, trehalose or maltose.
- 82. (Original) The composition of claim 80, wherein the polyol is inositol, ethylene glycol, glycerol, sorbitol, xylitol, mannitol or 2-methyl-2,4-pentane-diol.
- 83. (Original) The composition of claim 80, wherein the amino acid is Na glutamate, proline, alpha-alanine, beta-alanine, lysine-HCl or 4-hydroxyproline.
- 84. (Original) The composition of claim 80, wherein the polymer is polyethylene glycol, dextran or polyvinylpyrrolidone.

Confirmation No. 4456

85. (Original) The composition of claim 80, wherein the inorganic salt is sodium sulfate, ammonium sulfate, potassium phosphate, magnesium sulfate or sodium fluoride.

- 86. (Original) The composition of claim 80, wherein the organic salt is sodium acetate, sodium polyethylene, sodium caprylate, proprionate, lactate or succinate.
- 87. (Original) The composition of claim 79, where the antioxidant is ascorbic acid, an ascorbic acid derivative, butylated hydroxy anisole, butylated hydroxy toluene, alkylgallate, dithiothreitol (DTT), sodium meta-bisulfite, sodium bisulfite, sodium dithionite, sodium thioglycollic acid, sodium formaldehyde sulfoxylate, tocopherol, a tocopherol derivative, monothioglycerol or sodium sulfite.
- 88. (Original) The composition of claim 87, wherein the ascorbic acid derivative is ascorbylpalmitate, ascorbylstearate, sodium ascorbate or calcium ascorbate.
- 89. (Original) The composition of claim 87, wherein the tocopherol derivative is d-alpha tocopherol, d-alpha tocopherol acetate, dl-alpha tocopherol acetate, d-alpha tocopherol succinate, beta tocopherol, delta tocopherol, gamma tocopherol or d-alpha tocopherol polyoxyethylene glycol 1000 succinate.
- 90. (Original) The composition of claim 79, wherein the preservative is benzalkonium chloride, chlorobutanol, parabens, thimerosal, benzyl alcohol or phenol.

91-186. (Canceled)

187. (Currently Amended) A kit which comprises a composition comprising an isolated dimer of PSMA protein in a solution that has a pH in the range of 6 to 7.5, wherein the composition further comprises at least one type of metal ions, and at least one salt, wherein the at least one salt is present at a concentration in the range of 100mM to 300mM, and wherein the sequence of each PSMA protein comprises the sequence set forth as SEQ ID NO: 1, or a portion thereof the composition of elaim-1 and instructions for use.

- 188. (Currently Amended) A kit which comprises a composition comprising an isolated dimer of PSMA protein in a solution that has a pH in the range of 6 to 7.5, wherein the composition further comprises at least one type of metal ions, and at least one salt, wherein the at least one salt is present at a concentration in the range of 100mM to 300mM, and wherein the sequence of each PSMA protein comprises the sequence set forth as SEQ ID NO: 1, or a portion thereof the composition of elaim 22, an adjuvant and instructions for mixing.
- 189. (Original) The kit of claim 188, wherein the adjuvant is alum.
- 190. (Currently Amended) The[[A]] kit of claim 187 or 188, which further comprises the composition of claim 22, a diluent and instructions for mixing.
- 191. (Currently Amended) The kit of claim 187 or 188, wherein the composition is provided in a vial or ampoule with a septum or a syringe.
- 192. (Currently Amended) The kit of claim 187<u>or 188</u>, wherein the <u>kit further comprises a vial</u> composition is in <u>lyophilized form</u>.
- 193. (Currently Amended) A pharmaceutical composition comprising Thethe composition of claim 48[[1]], further comprising and a pharmaceutically acceptable carrier.
- 194. (New) The composition of claim 63, wherein the metal ions are calcium ions.
- 195. (New) The composition of claim 48, wherein the metal ions are calcium ions and magnesium ions.
- 196. (New) The composition of claim 48, wherein the sequence of each PSMA protein comprises the sequence of amino acids 44-750 of SEQ ID NO: 1.

- 197. (New) The composition of claim 48, wherein the sequence of each PSMA protein comprises the sequence of amino acids 58-750 of SEQ ID NO: 1.
- 198. (New) The composition of claim 48, wherein the sequence of each PSMA protein comprises the sequence of amino acids 601-750 of SEQ ID NO: 1.
- 199. (New) The composition of any of claims 48, 51-53, 60, 68, 194 or 195, wherein the sequence of each PSMA protein consists of the sequence of amino acids 44-750 of SEQ ID NO: 1.
- 200. (New) The composition of claim 48, wherein the composition comprises at least 0.25 molar equivalent metal ion to PSMA protein.
- 201. (New) The composition of claim 48, wherein the composition comprises at least 0.5 molar equivalent metal ion to PSMA protein.
- 202. (New) The composition of claim 48, wherein the composition comprises at least 1 molar equivalent metal ion to PSMA protein.
- 203. (New) The composition of claim 48, wherein the composition comprises a molar excess of metal ion to PSMA protein.
- 204. (New) The composition of claim 60, wherein the adjuvant is alum, monophosphoryl lipid A, an immunostimulatory oligonucleotide, incomplete Freund's adjuvant, complete Freund's adjuvant, a manide-oleate adjuvant, vitamin E, a water-in-oil emulsions prepared from a biodegradable oil, Quil A, a MPL and mycobacterial cell wall skeleton combination, Detox-B, CRL-1005, L-121, or alphagalactosylceramide.
- 205. (New) The composition of claim 204, wherein the adjuvant is alum.
- 206. (New) The composition of claim 48, wherein the composition further comprises a cytokine.

- 207. (New) The composition of claim 48, wherein the composition is sterile.
- 208. (New) A lyophilized form of a composition comprising an isolated dimer of PSMA protein in a solution that has a pH in the range of 6 to 7.5, wherein the composition further comprises at least one type of metal ions, and at least one salt, wherein the at least one salt is present at a concentration in the range of 100mM to 300mM, and wherein the sequence of each PSMA protein comprises the sequence set forth as SEQ ID NO: 1, or a portion thereof.
- 209. (New) The lyophilized form of claim 208, wherein the solution has a pH of 7.5.
- 210. (New) The lyophilized form of claim 208, wherein the solution has a pH of 7.
- 211. (New) The lyophilized form of claim 208, wherein the solution has a pH of 6.5.
- 212. (New) The lyophilized form of claim 208, wherein one component of the salt is sodium, potassium, ammonium, magnesium, calcium, or zinc, and wherein another component of the salt is chloride, sulfate, or acetate.
- 213. (New) The lyophilized form of claim 212, wherein the salt is sodium chloride, sodium sulfate, sodium acetate or ammonium sulfate.
- 214. (New) The lyophilized form of claim 208, wherein the salt is present at a concentration of 150mM.
- 215. (New) The lyophilized form of claim 208, wherein the metal ions are zinc ions, calcium ions, magnesium ions, cobalt ions, or manganese ions.
- 216. (New) The lyophilized form of claim 208, wherein the metal ions are zinc ions and calcium ions.

- 217. (New) The lyophilized form of claim 216, wherein the zinc ions and calcium ions are present at a concentration in the range of 0.1mM to 5mM.
- 218. (New) The lyophilized form of claim 216, wherein the zinc ions are present at a concentration that is lower than the concentration of the calcium ions.
- 219. (New) The lyophilized form of claim 218, wherein the zinc ions are present at a concentration of 0.1mM and the calcium ions are present at a concentration of 1mM.
- 220. (New) The lyophilized form of claim 215, wherein the metal ions are magnesium ions.
- 221. (New) The lyophilized form of claim 220, wherein the magnesium ions are present at a concentration in the range of 0.1mM to 5mM.
- 222. (New) The lyophilized form of claim 221, wherein the magnesium ions are present at a concentration of 0.5mM.
- 223. (New) The lyophilized form of claim 215, wherein the metal ions are calcium ions.
- 224. (New) The lyophilized form of claim 208, wherein the metal ions are calcium ions and magnesium ions.
- 225. (New) The lyophilized form of claim 208, wherein the composition comprises at least 0.25 molar equivalent metal ion to PSMA protein.
- 226. (New) The lyophilized form of claim 208, wherein the composition comprises at least 0.5 molar equivalent metal ion to PSMA protein.

- 227. (New) The lyophilized form of claim 208, wherein the composition comprises at least 1 molar equivalent metal ion to PSMA protein.
- 228. (New) The lyophilized form of claim 208, wherein the composition comprises a molar excess of metal ion to PSMA protein.
- 229. (New) The lyophilized form of claim 208, wherein the solution is free of chelating agents.
- 230. (New) The lyophilized form of claim 208, wherein the composition further comprises at least one adjuvant.
- 231. (New) The lyophilized form of claim 230, wherein the adjuvant is alum, monophosphoryl lipid A, an immunostimulatory oligonucleotide, incomplete Freund's adjuvant, complete Freund's adjuvant, a manide-oleate adjuvant, vitamin E, a water-in-oil emulsions prepared from a biodegradable oil, Quil A, a MPL and mycobacterial cell wall skeleton combination, Detox-B, CRL-1005, L-121, or alpha-galactosylceramide.
- 232. (New) The lyophilized form of claim 231, wherein the adjuvant is alum.
- 233. (New) The lyophilized form of claim 208, wherein the composition further comprises a cytokine.
- 234. (New) The lyophilized form of claim 208, wherein the sequence of each PSMA protein comprises the sequence of amino acids 44-750 of SEQ ID NO: 1.
- 235. (New) The lyophilized form of claim 208, wherein the sequence of each PSMA protein comprises the sequence of amino acids 58-750 of SEQ ID NO: 1.
- 236. (New) The lyophilized form of claim 208, wherein the sequence of each PSMA protein comprises the sequence of amino acids 601-750 of SEQ ID NO: 1.

- 237. (New) The lyophilized form of any of claims 208-211, 220, 223, 224 or 230, wherein the sequence of each PSMA protein consists of the sequence of amino acids 44-750 of SEQ ID NO: 1.
- 238. (New) The lyophilized form of claim 208, wherein the composition is physiologically acceptable.
- 239. (New) The lyophilized form of claim 208, wherein the composition further comprises a pharmaceutically acceptable carrier.
- 240. (New) The lyophilized form of claim 208, wherein the composition is sterile.
- 241. (New) The lyophilized form of claim 208, wherein the composition further comprises at least one buffer.
- 242. (New) The lyophilized form of claim 208, wherein the composition further comprises a surfactant.
- 243. (New) The lyophilized form of claim 208, wherein the composition further comprises a cryoprotectant, an antioxidant, or a preservative.
- 244. (New) A kit which comprises a lyophilized form of a composition comprising an isolated dimer of PSMA protein in a solution that has a pH in the range of 6 to 7.5, wherein the composition further comprises at least one type of metal ions, and at least one salt, wherein the at least one salt is present at a concentration in the range of 100mM to 300mM, and wherein the sequence of each PSMA protein comprises the sequence set forth as SEQ ID NO: 1, or a portion thereof, and instructions for use.
- 245. (New) A kit which comprises a lyophilized form of a composition comprising an isolated dimer of PSMA protein in a solution that has a pH in the range of 6 to 7.5, wherein the composition

further comprises at least one type of metal ions, and at least one salt, wherein the at least one salt is present at a concentration in the range of 100mM to 300mM, and wherein the sequence of each PSMA protein comprises the sequence set forth as SEQ ID NO: 1, or a portion thereof, an adjuvant and instructions for mixing.

22

- 246. (New) The kit of claim 245, wherein the adjuvant is alum.
- 247. (New) The kit of claim 244 or 245, which further comprises a diluent.
- 248. (New) The kit of claim 244 or 245, wherein the lyophilized form is provided in a vial or ampoule with a septum or a syringe.
- (New) The kit of claim 244 or 245, wherein the kit further comprises a vial. 249.
- 250. (New) A composition comprising an isolated dimer of PSMA protein in a solution that has a pH in the range of 6 to 7.5 and comprises:
  - (a) 5 to 20nM sodium phosphate,
  - (b) 100 to 300mM sodium chloride or sodium sulfate, and
  - (c) at least one type of metal ions;

wherein the sequence of each PSMA protein comprises the sequence set forth as amino acids 44-750 of SEQ ID NO: 1.

- 251. (New) The composition of claim 250, wherein the solution has a pH of 7.5.
- 252. (New) The composition of claim 250, wherein the solution has a pH of 7.
- 253. (New) The composition of claim 250, wherein the metal ions are zinc ions, calcium ions, magnesium ions, cobalt ions, or manganese ions.
- 254. (New) The composition of claim 253, wherein the metal ions are magnesium ions.

- 255. (New) The composition of claim 253, wherein the metal ions are calcium ions.
- 256. (New) The composition of claim 250, wherein the metal ions are calcium ions and magnesium ions.
- 257. (New) The composition of claim 250, wherein the composition further comprises at least one adjuvant.
- 258. (New) The composition of claim 257, wherein the adjuvant is alum, monophosphoryl lipid A, an immunostimulatory oligonucleotide, incomplete Freund's adjuvant, complete Freund's adjuvant, a manide-oleate adjuvant, vitamin E, a water-in-oil emulsions prepared from a biodegradable oil, Quil A, a MPL and mycobacterial cell wall skeleton combination, Detox-B, CRL-1005, L-121, or alphagalactosylceramide.
- 259. (New) The composition of any of claims 250-258, wherein the sequence of each PSMA protein consists of the sequence of amino acids 44-750 of SEQ ID NO: 1.
- 260. (New) The composition of claim 250, wherein the composition further comprises a cryoprotectant, an antioxidant, or a preservative.
- 261. (New) A kit which comprises instructions for use and a composition comprising an isolated dimer of PSMA protein in a solution that has a pH in the range of 6 to 7.5 and comprises:
  - (a) 5 to 20nM sodium phosphate,
  - (b) 100 to 300mM sodium chloride or sodium sulfate, and
  - (c) at least one type of metal ions;

wherein the sequence of each PSMA protein comprises the sequence set forth as amino acids 44-750 of SEQ ID NO: 1.

Application No. 10/695,667 Confirmation No. 4456

- 262. (New) A kit which comprises instructions for mixing, an adjuvant and a composition comprising an isolated dimer of PSMA protein in a solution that has a pH in the range of 6 to 7.5 and comprises:
  - (a) 5 to 20nM sodium phosphate,
  - (b) 100 to 300mM sodium chloride or sodium sulfate, and
  - (c) at least one type of metal ions;

wherein the sequence of each PSMA protein comprises the sequence set forth as amino acids 44-750 of SEQ ID NO: 1.

- 263. (New) The kit of claim 261 or 262, which further comprises a diluent.
- 264. (New) The kit of claim 261 or 262, wherein the composition is provided in a vial or ampoule with a septum or a syringe.
- 265. (New) The kit of claim 261 or 262, wherein the kit further comprises a vial.